IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

MARGARET HALTON PRIEST, Individually and as Representative of the Estate of Noel Lajoie Priest	)	
Plaintiff,	)	
vs.	)	CIVIL ACTION NO. 1:15-CV-00822-LY
SANDOZ, INC.	)	
Defendant.	)	

SANDOZ INC.'S MOTION TO EXCLUDE TESTIMONY OF DANIEL BUFFINGTON, PHARM.D. IN PART, WITH INCORPORATED MEMORANDUM OF LAW

Defendant Sandoz Inc. ("Sandoz") hereby files its Motion to Exclude Testimony of Daniel Buffington, Pharm.D. in part, pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny, for the reasons set forth below in the incorporated memorandum in support.

I. INTRODUCTION

The only claims remaining in this case after this Court's partial grant of Sandoz' Motions to Dismiss are claims of gross negligence and negligence per se, alleging Sandoz failed to provide a patient-directed Medication Guide to Plaintiff's decedent Noel Priest. ("Plaintiff's Decedent" or "Mr. Priest.") Plaintiff alleged "despite FDA requirements that the drug companies provide the patients Medication Guide with FDA written material with their Amiodarone prescription, no Medication Guide was provided to Noel Priest by Defendant" (Am. Compl. ¶ 123) and "if Noel Priest had been provided the Medication Guide he would not have taken Amiodarone for a non-life threatening, non-last resort condition – atrial fibrillation, and he would still be alive today" (*Id.* ¶ 124). Plaintiff further alleged by "failing

to provide a Medical (sic) Guide Defendant rendered the sale of its Amiodarone to Plaintiff (and others) illegal, and is guilty of negligence per se." (*Id.* ¶ 133.) Thus, Plaintiff's remaining causes of action criticize Sandoz' compliance with federal statutes and regulations governing Medication Guides for amiodarone.

Plaintiff's sole expert witness on this crucial topic of what federal law required of Sandoz and whether it complied is Daniel Buffington, Pharm.D., M.BA., who is a pharmacist and pharmacologist with no real training or experience in the federal regulation of Medication Guides. While Dr. Buffington has worked for decades as a pharmacist dispensing drugs and Medication Guides to patients, he has never worked at the U.S. Food and Drug Administration ("FDA") to review or approve Medication Guides, nor has he ever worked at a pharmaceutical company ensuring regulatory compliance with federal regulations regarding Medication Guides or authoring regulatory submissions to FDA pertaining to Medication Guides. At his deposition, he was unfamiliar with the method through which a drug manufacturer submits information about its Medication Guides to FDA for review, and ignored evidence in this case that Sandoz had made such submissions and repeatedly advised FDA of how it was both formatting and distributing its Medication Guides to distributors and pharmacies.

Instead, Dr. Buffington bases his unique opinions regarding what federal regulations and FDA require of pharmaceutical manufacturers solely on his interpretation of 21 C.F.R. §208.24, the regulation governing distribution of Medication Guides. This is plainly a legal conclusion disguised as an expert opinion, which is outside the role of an expert to provide. His sole support for his opinion that Sandoz could only comply with federal regulations governing Medication Guides by developing a nationwide compliance program to educate pharmacists about Medication Guides for amiodarone and validate they are being distributed is a PowerPoint presentation reflecting a comment by FDA that manufacturers are "ultimately

responsible" for Medication Guide distribution. But the language of the regulation itself is clear enough for this Court to interpret without expert assistance, and makes plain that a manufacturer's obligations end when it either distributes Medication Guides in adequate numbers to authorized dispensers and distributors, or when it makes available to authorized dispensers and distributors a means to obtain Medication Guides for distribution. Dr. Buffington chooses to ignore numerous other documents authored by FDA that directly contradict his interpretation of the regulations. This Court should exclude Dr. Buffington's opinions, as outlined in the proposed order submitted herewith, regarding drug manufacturers' regulatory obligations for Medication Guides and his opinions on whether Sandoz complied with such regulations for amiodarone, because (1) he is unqualified to offer them under Fed. R. Evid. 702, (2) they lack support and are unreliable under *Daubert*, and (3) he is attempting to impermissibly offer legal conclusions as expert opinions when only this Court may decide questions of law and he has no specialized training or expertise in interpretation of federal regulations to support his opinions.

II. FACTUAL BACKGROUND

Plaintiff has proffered Dr. Buffington as an expert witness regarding "Defendant's alleged failure to insure the dispensers of amiodarone or the patients received an FDA compliant MedGuide with each amiodarone prescription." Plaintiff's Expert Disclosure at 1.[1] Dr. Buffington is President and CEO of Clinical Pharmacology Services, Inc., a consulting firm that provides "drug information support and medication consult services" and "clinical research, medical education, and forensic pharmacology,"[2] and is also president of the non-profit American Institute of Pharmaceutical Sciences, which is intended to further "the

[1] A true and correct copy of Plaintiff's Expert Disclosure is attached as **Exhibit A**.
[2] A true and correct copy of the Clinical Pharmacology Services website is attached as **Exhibit B**.

development and utilization of optimal medication therapy management strategies."[3] *See* Curriculum Vitae of Daniel Buffington ("Buffington CV")[4]; *see also* July 31, 2017 Deposition of Daniel Buffington ("Buffington Dep.") at 53:11-16[5]. He is adjunct faculty at University of South Florida and Mercer University's departments of pharmacy and has served as a clinical professor of pharmacy for the University of Florida, Palm Beach Atlantic University, and Nova Southeastern University. *Id.* at 63:20-23. He is also a Faculty Research Participant and U.S. Health Care Reform team member for the Center for Medicare and Medicaid Services' Innovation Center. *See* Buffington CV; *see also* Buffington Dep. at 53:18-21. Dr. Buffington has testified at trial as an expert approximately 200 times and has been deposed as an expert nearly as often. *Id*. at 9:20-11:4, although his primary testimony has been as a pharmacologist, toxicologist or pharmacist rather than regulatory matters. *Id.* at 30:21-31:5; 164:4-8

Dr. Buffington's opinions in this matter fall within three categories. ***First***, he offers the opinion that Sandoz' four-part cut-away format for its amiodarone Medication Guide failed to comply with FDA regulations, because he believes Sandoz did not make clear to pharmacists how the Medication Guides should be distributed to patients. *Id*. at 235:19-238:16; 246:20-247:9. ***Second***, he offers the opinion that any format of Medication Guide Sandoz could have utilized still would not be compliant with federal regulations unless it includes both a comprehensive program to educate pharmacists on Medication Guides and a validation program to ensure patients are receiving Medication Guides. *Id*. at 194:4-195:17; 240:6-242:14. ***Third***, with respect to the parts of 21 C.F.R. §208.24 that impose obligations on authorized

[3] A true and correct copy of the American Institute of Pharmaceutical Services website is attached as **Exhibit C**.
[4] A true and correct copy of Dr. Buffington's Curriculum Vitae is attached as **Exhibit D**.
[5] A true and correct copy of cited excerpts from Dr. Buffington's deposition is attached as **Exhibit E**. Because it contains testimony and exhibits that include trade secret, confidential, research, proprietary, developmental and/or non-public commercial information of Sandoz, excerpts of Dr. Buffington's deposition were filed under seal as **Exhibit E** to Defendant's Motion to Seal Exhibits to Motion to Exclude the Testimony of Daniel Buffington, Pharm.D. in Part, filed contemporaneously herewith, and the confidential exhibits were filed as **Exhibits F-J**, **L**, and **N** to the Motion to Seal. Throughout this memorandum of law, any references to these exhibits refer to the documents attached to the Motion to Seal as **Exhibits E-J**, **L**, and **N**.

dispensers—which are pharmacies, per the definition in 21 C.F.R. §208.3(a)—to ensure Medication Guides provided by manufacturers such as Sandoz actually travel through the distribution chain all the way to patients, Dr. Buffington offers the opinion that these regulations are not actually binding on pharmacies because he does not believe they are subject to FDA's jurisdiction, and instead he believes manufacturers alone are responsible for ensuring their Medication Guides travel through the distribution chain all the way to patients. *Id*. at 95:9-96:5; 99:13-19; 137:21-24; 172:5-8; 184:3-16; 199:2-15; 250:3-8; 270:16-273:25.[6]

Each of these opinions should be excluded because (1) Dr. Buffington lacks the qualifications, training or experience om FDA regulation of pharmaceutical manufacturers or Medication Guides to have any basis for such opinions; (2) they are not reliable, adequately supported by recognized research, or otherwise admissible under *Daubert*; and (3) these "opinions" are ultimately legal conclusions interpreting federal regulations, which only this Court may interpret, and on which expert testimony is inadmissible.

III. ARGUMENT

A. Federal Rule of Evidence 702, as Interpreted by *Daubert v. Merrell Dow Pharmaceuticals, Inc*., Governs the Admissibility of Expert Testimony.

Pursuant to the Federal Rules of Evidence, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 275 (5th Cir. 1998); *see also In re Silica Products Liability Litigation*, 398 F. Supp. 2d 563, 620 (S.D. Tex 2005). Federal Rule of Evidence 702 is the "primary locus of this obligation." *In re Silica*, 398 F. Supp. 2d at 620. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an

[6] There may be topics on which Dr. Buffington could be qualified as an expert, including the practice of pharmacy in Florida and the clinical pharmacology of amiodarone, but Sandoz is not moving to exclude such opinions. He disclaimed intent to testify about pharmacology in this case, Buffington Dep.86:13-16; 291:19-292:7; 50:2-5, and he is not licensed to practice in Texas, where Mr. Priest's prescriptions were dispensed. *See* Buffington CV.

> expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

In *Daubert*, the United States Supreme Court provided the analytical framework for courts to utilize under Rule 702. *See* 509 U.S. 579, 589-95 (1993); *see also U.S. v. Hicks*, 389 F.3d 514, 525 (5th Cir. 2004). Under this framework, district courts "act as gate-keepers overseeing the admission of scientific and non-scientific expert testimony." *Burleson v. Texas Dep't of Criminal Justice*, 393 F.3d 577, 583 (5th Cir. 2004) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999)); *see also In re Silica*, 398 F. Supp. 2d at 621.

Rule 702 first requires the district court to determine whether the purported expert witness is qualified to give the proffered testimony. *U.S. v. Abdallah*, 629 F. Supp. 2d 699, 749 (S.D. Tex. 2009). To be qualified as an expert, a witness must "possess specialized knowledge, skill, experience, training, or education" in the area on which the expert seeks to opine. *Id.* (citing Fed. R. Evid. 702). Thus, "[t]he court must determine whether the proposed expert's training or experience are sufficiently related to the issues and evidence before the court that the expert's testimony will assist the trier of fact." *Abdallah*, 629 F. Supp. 2d. at 749.

If the purported expert is determined to be qualified, the district court must next determine if the expert's testimony is both relevant and reliable before it will be admitted. *Id.* at 749-50. The proponent of the expert testimony bears the burden of demonstrating the expert's findings and conclusions are reliable and admissible under Rule 702. *See Moore*, 151 F.3d at 276. This burden is not satisfied by the expert witness' "assurances that he has utilized generally accepted scientific methodology." *Id.* Rather, the proponent bears the burden to "prove by a preponderance of the evidence that the testimony is reliable." *Id*. In the context of regulatory opinions, a qualified regulatory expert's opinions must have a basis in the

regulations themselves and not be the expert's personal opinions. *Lofton v. McNeil Consumer & Specialty Pharm.*, No. CIV.A. 3:05CV1531LBH, 2008 WL 4878066, at *7 (N.D. Tex. July 25, 2008), objections overruled, 682 F. Supp. 2d 662 (N.D. Tex. 2010), aff'd, 672 F.3d 372 (5th Cir. 2012) (plaintiff experts' "personal opinions . . . are inadmissible because they do not meet the *Daubert* requirements for reliability"). An expert also must "provide some analysis, opinion or expertise when testifying about FDA regulatory process and drug labeling." *Johnson v. Wyeth LLC*, CV 10-02690-PHXFJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012) (excluding opinion on the regulatory requirement of a post-release safety study where "[p]laintiff was unable to point to anywhere in [expert reports] that identify any FDA regulations or rules requiring defendants to test their HRT drugs after they were released").

Thus, to be reliable, proposed expert opinions must be "supported by appropriate validation" and not be based on the purported expert's "subjective belief or unsupported speculation." *Moore*, 151 F.3d at 275. Further, "incorrect assumptions critical to an expert's opinion make that opinion unreliable," including assumption of the existence of a particular legal duty. *Whitney Nat. Bank v. Air Ambulance by B & C Flight Mgmt., Inc.*, 516 F. Supp. 2d 802, 816-817 (S.D. Tex. 2007) (citing *Moore*, 151 F.3d 269). A purported expert witness's "use of a general methodology cannot vindicate a conclusion for which there is no underlying . . . support." *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999).

B. This Court Should Exclude Dr. Buffington's Opinions Because He Is Not Qualified to Offer Them and His Opinions Are Unreliable.

This Court should exclude Dr. Buffington's opinions regarding FDA Medication Guide regulations and whether Sandoz complied with them, because: (1) Dr. Buffington is not qualified to offer opinions about Sandoz' federal regulatory obligations for Medication Guides, and (2) his opinions interpreting FDA's Medication Guide regulations and his opinions as to

whether Sandoz complied with such regulations are based on improper methodology and are therefore unreliable under Fed. R. Evid. 702 and *Daubert*.

1. Dr. Buffington Lacks the Requisite Qualifications, Training or Experience to Opine About Federal Medication Guide Regulations.

Dr. Buffington does not satisfy *Daubert*'s threshold requirement of being qualified as an expert to provide his opinions interpreting the federal Medication Guide regulations. Federal courts require more than just some training in a particular field for an expert to be considered qualified. For example, in *Houston-Hines v. Houston Indep. Sch. Dist.*, the proffered expert had twenty-nine years of experience in law enforcement and security experience; however, he did not have "experience or training in the unique challenges of law enforcement in a school setting," and thus was unqualified to provide an expert opinion regarding an arresting officer's performance in a school setting. No. CIV.A. H-04-3539, 2006 WL 897209, at *2-*3 (S.D. Tex. Apr. 4, 2006). The court reasoned the proffered expert's experience, though extensive, was not sufficiently related to the particular issue on which he proposed to testify. *Id*. Thus, the *Houston-Hines* court held, to qualify an expert witness the proponent of the witness must demonstrate by a preponderance of the evidence that the expert testimony is admissible. *See id*. at *3; *see also Wilson v. Woods*, 163 F.3d 935, 938 (5th Cir. 1999) (excluding testimony of purported expert whose qualifications were insufficiently related to his proposed testimony).

Like the proposed expert in *Houston-Hines*, Dr. Buffington's experience as a pharmacist and pharmacologist is not sufficiently related to the subject matter on which he seeks expert qualification. Dr. Buffington admits he has not previously been qualified as or testified as an expert regarding regulations applicable to Medication Guides. Buffington Dep. 30:21-31:5; 164:4-8. He has no experience working at FDA and none of his work consulting with the Center for Medicare and Medicaid Services or any other agency involved

pharmaceutical labeling or Medication Guides. *Id*. at 167:13-19. He has not drafted a Medication Guide. *Id*. at 40:15-16. He has not authored any labeling change submission to FDA or any regulatory submission to FDA for any purpose. *Id*. at 40:17-19. While he has done pharmacology and pharmacy consulting work for several pharmaceutical companies, he has never reviewed a Medication Guide to ensure it complies with applicable regulations. *Id*. at 61:15-19. Instead, his pharmaceutical consulting "would be either in an educational role helping to develop continuing education materials. Following that . . . clinical research design and serving as an investigator. Following that would be market research, patient satisfaction research, reimbursement, review analysis of postmarketing surveillance data." *Id*. at 41:22-42:7. In sum, Dr. Buffington does not have sufficient experience with Medication Guide regulations to qualify him as an expert about those regulations.

And yet, FDA's regulation of pharmaceutical manufacturers, distributors and dispensers with respect to Medication Guides is the very crux of the topics on which Dr. Buffington intends to testify at trial. Because Sandoz is a generic drug manufacturer, its amiodarone Medication Guide must be identical at all times to the Medication Guide of the Reference Listed Drug ("RLD"), Cordarone®. In December 2004, FDA first required a Medication Guide for Cordarone®. *See* Affidavit of Gregory Seitz, ("Seitz Aff."), attached as **Exhibit F**, at ¶ 25. On January 21, 2005, FDA notified Sandoz' subsidiary Eon Labs, Inc. ("Eon") of the new Medication Guide required for amiodarone, and on January 24, 2005, Eon submitted a Changes Being Effected ("CBE") letter to FDA with its proposed Medication Guide.[7] *Id.* ¶ 30. Sandoz' Medication Guide was originally submitted to FDA through the CBE process, and subsequent updates to the Medication Guide have occurred through the same process.

However, at his deposition, Dr. Buffington testified he did not know what a CBE was.

[7] A true and correct copy of the January 24, 2005 CBE is attached as **Exhibit G**.

Buffington Dep. 26:20-21. He initially refused to answer questions about the CBE process, stating he would need to consult with FDA to answer such questions. *Id*. at 127: 14-18; 128:16-25; 129:2-6. While he later reviewed CBE documents marked as exhibits and claimed he "know[s] what a CBE is, and this looks like a CBE," he admitted it is "not something [he is] grossly familiar with," and he is "not an expert on the CBE process," but planned to become one before trial by speaking to "colleagues at FDA." *Id*. at 128:7-15; 216:6-11.

Dr. Buffington's unfamiliarity with the CBE process—the method by which Sandoz advised FDA of its compliance with Medication Guide regulations in content, format, distribution method and other aspects—should doom these opinions. He presumes Sandoz was using a non-compliant format for its Medication Guides due to the four-part folded "cut-away" "outsert" affixed to each bottle of amiodarone, and also presumes Sandoz did not make FDA aware it was using such methods to distribute Medication Guides for amiodarone. Yet, the CBE documents produced in this case and shown to Dr. Buffington at his deposition show clearly that his presumptions are incorrect, and in fact Sandoz' CBE submissions advised FDA that Sandoz was using a four-part cut-away Medication Guide folded into a 1" square and affixed to each bottle, and further advised of the specific number to be distributed with each shipment depending on bottle size. That Dr. Buffington did not even know what these documents were initially, when they directly contradict his opinions about FDA's awareness of how Sandoz was complying with the Medication Guide regulations, makes abundantly clear that he lacks the requisite qualifications, training or experience to offer opinions about Sandoz' Medication Guide obligations and whether it complied with them for its amiodarone Medication Guides.

Dr. Buffington essentially attempts to qualify himself to offer these opinions by stating that he is a pharmacist and a professor of pharmacy, and "the entire profession of pharmacy is dictated by FDA regulations with regards to products that are approved by FDA." *Id.* at

165:19-25. If this were true, any pharmacist or pharmacy professor could be qualified as an expert on any FDA regulation of pharmaceuticals, which is an absurd proposition. Moreover, his lack of familiarity with and misunderstanding of key concepts critical to FDA regulations relating to Medication Guides shows clearly that his work with pharmaceutical products in other areas has not given him the requisite knowledge to be qualified as an expert on pharmaceutical regulations. His professional career as a consultant and expert witness in the areas of pharmacology, toxicology and pharmacy does not rise to the level of specialized training or experience in FDA's Medication Guide regulations to qualify him under *Daubert* to provide expert opinion upon the matters for which he seeks to testify.

2. Dr. Buffington's Opinions on Whether Sandoz' Cut-Away Medication Guides Comply with Federal Law Are Unsupported and His Methodology Is Unreliable.

Even if he were qualified to opine about federal Medication Guide regulations and whether a Sandoz' Medication Guides complied with them, Dr. Buffington's opinions on whether Sandoz' four-part cut-away Medication Guides comply with federal regulatory requirements are unreliable, because they are founded upon a critical incorrect assumption and are plainly contrary to the obvious meaning of the regulations. *See Whitney*, 516 F. Supp. 2d at 817 ("Incorrect assumptions critical to an expert's opinion make that opinion unreliable."); *see also Lofton*, 2008 WL 4878066, at *6-7 (experts' opinions were unreliable when they were experts' personal opinions that had no basis in FDA regulations). Dr. Buffington states "this document [Sandoz' four-part cut-away Medication Guide for amiodarone] is not a med guide consistent with dispensing to a patient." Buffington Dep. 236:16-19. Despite seeing similar Medication Guides in practice as a retail pharmacist, he claims he would not dispense them to a patient, because in his opinion it is "a package insert blended in print with med guide content. That is not a med guide." *Id*. at 238:17-239:3. He also claims Sandoz' cut-away Medication

Guide format is not compliant because an authorized dispenser pharmacist has to "cut, assemble, modify some original document," by unfolding the attached outsert and cutting one of the four identical Medication Guide strips along the cut marks to give to a patient with their prescription. *Id.* at 246:7-19. This is plainly a personal opinion with no basis or support.

Dr. Buffington's opinions on whether the four-part cut-away Medication Guide complies with regulations ignore evidence produced in this case that FDA was well aware Sandoz was using this format. Dr. Buffington opines that Sandoz' CBE submissions to FDA, which included the cut-away Medication Guide format, were insufficient to put FDA on notice of Defendant's intent to utilize that format for Medication Guides to be distributed to patients. *Id*. at 133:19-23.[8] Yet, he acknowledged Sandoz' Annual Reports to FDA also included the cut-away Medication Guide. *Id*. at 214:11-14.[9] Dr. Buffington even admits he did not find any instances where FDA ever notified Sandoz the cut-away Medication Guides were non-complaint or should be modified, even though FDA had authority to make such a determination and require changes to the Medication Guide if found to be non-compliant. *Id*. at 134:12-19.

Unsurprisingly, given his lack of familiarity with the CBE process, Dr. Buffington's opinions show a fundamental misunderstanding of the process for notifying FDA of changes to an approved Medication Guide. Per FDA regulations, a manufacturer is limited as to what topics can be addressed in a CBE-0 (for changes being implemented immediately) and a CBE-30 (for changes to be implemented after 30 days). *See* 21 C.F.R. § 314.70(c)(3); Center for Drug Evaluation and Research, FDA, Guidance for Industry, Changes to an Approved NDA or ANDA, at 24-26 (2004).[10] By definition, a manufacturer does not need to obtain FDA approval before distributing a product changed via a CBE, although a CBE-30 requires a manufacturer

[8] A true and correct copy of the January 31, 2012 CBE is attached as **Exhibit H**.
[9] True and correct copies of Annual Reports for 12/01/11 to 11/30/12 (SANDOZ-AMIO-ANNRPTS-002480) and 12/01/12 to 11/30/13 (SANDOZ-AMIO-ANNRPTS-002657) are attached as **Exhibit I** and **Exhibit J**.
[10] A true and correct copy of this Guidance is attached as **Exhibit K**.

to wait 30 days to implement such changes. After review of the CBE, FDA may order the manufacturer to cease distribution of the products with the changes indicated in the CBE. 21 C.F.R. § 314.70(c)(7). However, per documents shown to Dr. Buffington at his deposition, on numerous occasions Sandoz submitted the cut-away Medication Guide in its Annual Reports and CBEs to FDA, and he could not locate any evidence indicating FDA ever disapproved of or required format changes to the cut-away Medication Guide. Buffington Dep. 134:12-19.

In discussing the multiple CBEs in which Sandoz informed FDA of changes to its Medication Guide format, content, and distribution plan, Dr. Buffington acknowledged the cut-away Medication Guide was included in the submission with a cover sheet stating "Final Printed Labeling," but he based his opinion that the Medication Guide was non-compliant on the fact that the four-part cut-away Medication Guide does not "say as exclusively for distributing to a patient." *Id*. at 132:10-21. Dr. Buffington further claims Sandoz created a misperception in its Annual Reports by also including the Medication Guide in a tear-away pad format, which he believes led FDA to infer tear-away pads would be distributed with all Sandoz amiodarone. *Id*. at 148:18-149:14. However, this opinion is clearly contradicted by Sandoz' June 8, 2010 CBE informing FDA it would only distribute Medication Guides in pad form with 500-count bottles. *Id*. at 124:20-126:4.[11] Therefore, Dr. Buffington's opinions on Sandoz' alleged non-compliance were directly disproven through documents shown at his deposition, yet he stands by such opinions, which are unreliable and should be excluded.

3. Dr. Buffington's Opinion that Sandoz Failed to Comply with FDA Regulations Because It Did Not Establish Educational Programs Is Factually Unsupported and the Methodology Underlying His Opinion Is Unreliable.

As with his opinions on format and method of distribution of Medication Guides, Dr. Buffington's opinion that Sandoz failed to comply with applicable regulations by not

[11] A true and correct copy of the June 8, 2010 CBE is attached as **Exhibit L**.

establishing a nationwide education and validation program for Medication Guides must also be excluded, because it is inconsistent with a reading of the plain language of the regulation, and the methodology underlying it is unreliable. This opinion is based on critical incorrect assumptions and does not have a basis in the relevant regulations. *See Whitney*, 516 F. Supp. 2d at 817 ("Incorrect assumptions critical to an expert's opinion make that opinion unreliable."); *see also Lofton*, 2008 WL 4878066, at *6-7 (experts' opinions unreliable when they are personal opinions and have no basis in FDA regulations).

Dr. Buffington opines that to comply with the Medication Guide regulations, Sandoz would need to develop a program of:

> "[o]utreach to the pharmacy community who are primary authorized dispensers, educational campaigns, improved accessibility for not reorder but technical assistance. The testimony I saw is that they only have someone who you can call and order more pads, but no one who does the technical assistance to explain to a pharmacy what are my – what are the options, what are the means."

Buffington Dep. 194:12-195:12. Dr. Buffington claims his reading of the federal regulations and FDA guidance documents support his opinion that such education and validation programs are required of all manufacturers of drugs for which FDA requires Medication Guides, though he cannot point to any specific FDA document stating such a requirement. *Id*. at 243:8-14. He believes all manufacturers have a legal obligation to educate pharmacists on the distribution of a manufacturer's Medication Guide to patients, because "it's the culmination of their duty, their responsibility per the regulation." *Id*. at 246:20-247:9. He bases his opinions about manufacturers' "duty" and "responsibility" on purported past statements by FDA at one public meeting and in a series of letters to manufacturers, in which FDA stated broadly that manufacturers are ultimately responsible for production and distribution of Medication Guides. *Id.* at 270:16-271:18. FDA may have made such a statement, but that does not translate into the duty to create a nationwide education and validation program that Dr. Buffington reads into

this relatively benign proposition He even admits neither the regulations nor FDA's purported public statements specifically reference a duty to educate pharmacists. *Id*. at 271:19-23. He also admits there is no legal source such as "a regulation, a guidance, [or] a statute" to support his proffered opinion that federal law requires a manufacturer to educate pharmacists regarding the obligation to distribute Medication Guides. *Id*. at 272:5-24.

Instead, Dr. Buffington entirely bases his opinion that such a duty exists on the use of the word "ensure" in 21 C.F.R. §208.24(b), effectively conceding this opinion has no corroborating support whatsoever. Buffington's opinion that compliance with federal law requires an education or validation program for Medication Guides is obviously wrong on its face, lacks any factual or legal support, and is based solely on his individual interpretation of the regulations. Dr. Buffington cannot point to any published research or analysis either from FDA or within the field of pharmaceutical regulation to support this opinion recognizing an entirely new regulatory duty, which is unsupported by the facts and a plain reading of the regulation, and is also unsupported by any reliable methodology and should be excluded.

4. Dr. Buffington's Opinion that Pharmacies Are Not Regulated by FDA Is Unreliable and Contrary to Governing Law.

When asked about 21 C.F.R. §208.24(d) describing the Medication Guide obligations of "authorized dispensers," which are essentially pharmacies, Dr. Buffington opines that the regulations are not binding on pharmacies, so in his opinion this portion of the regulation does not impose an obligation on pharmacies to ensure patients actually receive Medication Guides. Buffington Dep. 95:22-96:5; 99:11-19. This opinion is based on critical incorrect assumptions and is directly contradicted by the language of the regulations and FDA's own statements of its authority to regulate pharmacies, so it should also be excluded.[12]

[12] *See Whitney*, 516 F. Supp. 2d at 817 ("Incorrect assumptions critical to an expert's opinion make that opinion unreliable."); *see also Lofton*, 2008 WL 4878066, at *6-7 (experts' opinions were unreliable when they were

Dr. Buffington stated that in his opinion FDA does not have authority over pharmacies with respect to Medication Guides, even though the regulations clearly impose obligations on authorized dispensers, which are pharmacies. *Id*. He testified there is no FDA jurisdiction to require a pharmacist to dispense a Medication Guide. *Id*. at 137:21-24. Because he believes a federal regulation cannot require a pharmacy to dispense a Medication Guide, he claims FDA is merely making a request or a recommendation by directing a portion of 21 C.F.R. §208.24 to pharmacies. *Id*. at 138:4-10; 184:3-10. Dr. Buffington repeatedly stated that FDA conceded it does not have jurisdiction over pharmacies to require pharmacists to dispense Medication Guides, but provided no support for this opinion. *See, e.g.*, *id.* at 184:3-16.

However, FDA's statements in the Federal Register regarding Medication Guide regulations contradict Dr. Buffington's opinion on whether it has legal authority to regulate pharmacies. FDA acknowledged that public comments to the proposal questioned whether FDA had jurisdiction over pharmacies, but FDA did "not agree that it lacks statutory authority over written information about prescription drug products that is dispensed by pharmacists." *See* Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66,378 (Dec. 1, 1998) (to be codified at 21 C.F.R. pt. 208).[13] In fact, in the Federal Register notice announcing the Medication Guide regulations, FDA stated "[f]ederal courts have affirmed FDA's authority to require the dispensing of patient labeling for prescription drugs, and that such requirement does not interfere with the practice of medicine." *Id.* at 66,382.[14]

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experts' personal opinions had no basis in FDA regulations); *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, No. 2:12-CV-07263, 2016 WL 4538621, at *6-7 (E.D. Pa. Aug. 31, 2016) (excluding expert opinions where opinions were contrary to governing law); *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *18 (E.D. Pa. Feb. 1, 2001) (testimony contrary to "controlling law as reflected in those regulations" is not "an 'expert' opinion, but rather a personal opinion about what standards [the expert] believes should apply" and should therefore be excluded).

[13] A true and correct copy of 63 Fed. Reg. 66,378 is attached as **Exhibit M**.

[14] The Federal Register notice also cites to *Pharmaceutical Mfr. Ass'n v. FDA*, 484 F. Supp. 1179 (D. Del. 1980), aff'd per curiam, 634 F. 2d 106 (3d Cir. 1980), as support for its authority to regulate pharmacies. Additionally, in a relatively recent guidance document, FDA again indicated that a "Medication Guide **must** be provided to the

Given FDA's public declarations of its authority in the Federal Register and the cases cited therein upholding its authority to regulate pharmacies' distribution of Medication Guides to patients, Dr. Buffington's opinions are directly contradicted by rather than being grounded in or supported by the relevant regulations, and should therefore be excluded. *Lofton*, 2008 WL 4878066, at *6-7 (excluding expert's personal opinions that had no basis in FDA regulations).

C. Dr. Buffington's Opinions Interpreting Federal Regulations Are Legal Conclusions that Invade the Roles of Court and Jury, and Must Be Excluded.

In addition to failing the qualifications and reliability tests, Dr. Buffington's opinions interpreting federal Medication Guide regulations and opinions on whether Sandoz complied with those regulations are ultimately legal conclusions that an expert witness may not offer at trial. Opinions interpreting the meaning and applicability of federal regulations and a defendant's standard of care and intent with regard to following regulations are impermissible legal conclusions, and should be excluded pursuant to Federal Rule of Evidence 704. *See Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir. 1983) (Rule 704 is not "intended to allow a witness to give legal conclusions."); *Berckeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006) ("an expert witness is prohibited from rendering a legal opinion.").

1. Dr. Buffington's Interpretations of Medication Guide Regulations Are Inadmissible Legal Conclusions.

Dr. Buffington's opinions in this case regarding what federal regulations require of manufacturers like Sandoz with respect to Medication Guides are ultimately just his personal interpretations of those regulations, which are unsupported and impermissible legal conclusions. Federal courts have held repeatedly that experts may not testify regarding legal interpretation of regulations, which is "the province of the court." *Silverman v. Watson Pharm.,*

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patient or the patient's agent . . . [w]hen a drug is dispensed in an outpatient setting (e.g. retail pharmacy, hospital ambulatory care pharmacy)." *See* Center for Drug Evaluation and Research, FDA, Guidance, Medication Guides – Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS), at 6 (2011).

Inc., 2013 WL 1413782, at *3 (S.D. Tex. Apr. 8, 2013). Instead, for opinions regarding federal regulations to be admissible, the expert must provide some specialized analysis, opinion, or expertise about the regulations, beyond merely interpreting their legal meaning.[15]

However, Plaintiff cannot articulate any additional analysis, opinion, or expertise that Dr. Buffington can offer about the relevant FDA regulations for Medication Guides that would justify allowing him to attempt to interpret them for the jury. Because he lacks any specialized experience or expertise with the federal regulatory requirements for Medication Guides, Dr. Buffington instead resorts to summarizing publicly available documents and providing his own take on what they mean and what actions he believes Sandoz should have taken instead.

Courts routinely have excluded expert opinions that are mere interpretations of federal regulations governing pharmaceutical manufacturers. In *In re Prempro Products Liability Litigation*, the Court excluded the testimony of a pharmaceutical regulatory expert whose testimony essentially amounted to summarizing regulatory documents for the jury. 554 F. Supp. 2d 871, 880 (E.D. Ark. 2008) ("The testimony was simply a regurgitation of an exhibit, absent any expert analysis or opinion . . . [the expert] simply read and summarized the documents, as any layperson could have done."). The *Prempro* court excluded the "regulatory expert" testimony, because "[the expert] again read selected excerpts from the documents, but provided no analysis which would require regulatory expertise—or any expertise." *Id.* at 882.

Similarly, where an expert seeks to opine that a defendant violated FDA regulations, courts have routinely excluded such opinions as impermissible legal conclusions. *See, e.g.,*

[15] *Johnson v. Wyeth LLC*, CV 10-02690-PHXFJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (limiting expert testimony on exhibits to "explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge"); *see also Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1330 (M.D. Fla. 2015) ("The Court will not permit [an expert] to testify to 'simple inferences drawn from uncomplicated facts that serve only to buttress plaintiff's theory of the case.'") (quoting *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 548-549 (S.D.N.Y. 2004)).

Kruszka v. Novartis Pharm. Corp., 28 F. Supp. 3d 920, 934 (D. Minn. 2014) ("of course, attempts by [plaintiff's regulatory expert] to offer an opinion as to whether Novartis violated the law with respect to FDA [regulations] constitute a legal conclusion and are not admissible."); *Stanley v. Novartis Pharm. Corp.*, 2014 WL 12573393, *4 (C.D. Cal. May 6, 2014) (same); *Wolfe v. McNeill-PPC, Inc.*, 881 F.Supp. 2d 650, 661-62 (E.D. Pa. 2012) (excluding from pharmaceutical case testimony by plaintiff's regulatory expert that defendant was negligent or its drug was unreasonably dangerous, because such testimony is impermissible legal opinion). This Court should reach the same conclusion on Dr. Buffington.

Dr. Buffington's expert report and deposition make clear he intends to opine that the Medication Guide regulations imposed certain obligations on Sandoz, Sandoz failed to comply, and was therefore negligent, all of which are impermissible legal conclusions. *See* June 5, 2017 Buffington Report, at pp. 1-2, attached as **Exhibit N**. Only this Court may interpret FDA regulations, and only the jury may decide whether Sandoz complied with those regulations or was negligent.[16] These legal conclusions masquerading as expert opinions should be excluded.

2. Dr. Buffington's Opinions Regarding Sandoz' Standard of Care and Intent Are Impermissible and Should Be Excluded.

Courts have repeatedly held that "allowing an expert to give his opinion on the legal conclusion[s] to be drawn from the evidence both invades the court's province and is irrelevant." *Taylor Pipeline Constr., Inc. v. Directional Rd. Boring, Inc.*, 438 F. Supp. 2d 696,

[16] *See also Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009) ("[a]n expert may never render conclusions of law."); *Owen*, 698 F.2d at 240 ("Moreover, allowing an expert to give his opinion on the legal conclusions to be drawn from the evidence both invades the court's province and is irrelevant."); *Neutrino Dev. Corp. v. Sonosite, Inc.*, 410 F. Supp. 2d 529, 545-46 (S.D. Tex. 2006) (expert testimony expounding upon what the law requires is "unnecessary and improper."); *Lincoln Gen. Ins. Co. v. Valley Transp. Brokerage, Inc.,* 2002 WL 34370100, at *5 (S.D. Tex. July 22, 2002) ("[Expert]'s proposed testimony would impermissibly invade both the court's province to instruct the jury on the law and the jury's decision-making function by instructing the jury how to apply the facts to the court's legal instructions."); *see also Aubrey v. Barlin*, 2015 WL 6002260, at *13 (W.D. Tex. Oct. 14, 2015) (where proposed expert's conclusions "amount to his application of the facts to the relevant securities laws, expert testimony "must be excluded as an improper rendering of legal conclusions"); *Mumford v. State Farm Mut. Auto. Ins. Co.*, 2015 WL 11110599, at *4 (E.D. Tex. July 30, 2015) (where proposed expert opined defendant had "duty" and "failed miserably," "it amounts to a conclusion of law").

706 (E.D. Tex. 2006) (quoting *Owen*, 698 F.2d at 240). For this reason, experts are not permitted to opine about the ultimate legal conclusions in a case, including a defendant's intent or whether a defendant breached a standard of care. *See C P Interests, Inc. v. Cal. Pools, Inc.*, 238 F.3d 690, 697 (5th Cir. Tex. 2001); *Diamond Offshore Co. v. Survival Sys. Int'l, Inc.*, 2013 WL 371648, at *8 (S.D. Tex. Jan. 29, 2013) (Expert's conclusion that a party "breached its duty of care and acted negligently is clearly a legal conclusion and should be excluded.").

However, Dr. Buffington's report and deposition demonstrate that he plans to testify regarding Sandoz' standard of care with respect to the Medication Guide regulations and whether it breached that standard. When asked to describe his opinions generally, he responds that his testimony "would be predominantly focused on the elaboration and illustration that the intent of the regulation and what was corporately decided and done as process by Sandoz with regards to development and distribution and validating their duty fell below the standard of care or were negligent, which ultimately limited patients' ability to receive med guides." Buffington Dep. 86:4-12. In addition to being nearly incomprehensible, such legal conclusions about a defendant's compliance with a purported standard of care are impermissible, because they invade a decision that is the exclusive province of the jury to weigh and decide at trial.

Dr. Buffington should not be permitted to provide his own unique interpretation of federal regulations in the guise of an expert opinion, when only this Court may interpret federal regulations and only the jury may apply such interpretation to the facts in reaching a verdict. These opinions should be excluded prior to trial.

IV. CONCLUSION

For the foregoing reasons, Sandoz respectfully asks this Court to exclude the expert opinions of Dr. Buffington as outlined in the proposed order submitted herewith. Because the issues presented in this motion are complex, Sandoz requests a hearing per L.R. 7(h).

Respectfully submitted this 22nd day of September, 2017.

/s/ *Sara K. Thompson*

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CERTIFICATE OF CONFERENCE

I hereby certify that counsel for Plaintiff has indicated that they oppose this motion.

/s/ *Sara K. Thompson*

CERTIFICATE OF SERVICE

I hereby certify that this document was served via mail and email on this 22nd day of September, 2017:

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